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| 10/562,745 | 10/26/2006 | Zahi A. Fayad | 112447.00003 | 4202 |

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| EXAMINER |
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DANG, DUY M

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| ART UNIT | PAPER NUMBER |
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2624

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09/25/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/562,745 | Applicant(s) FAYAD ET AL. | |
| | Examiner Duy M. Dang | Art Unit 2624 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 October 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/29/2005</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 1-19 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

All method claims 1-19 are rejected under 35 U.S.C. 101 as not falling within one of the four statutory categories of invention. Supreme Court precedent (See *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876)) and recent Federal Circuit decisions (See *In re Bilski*, 88 USPQ2d 1385 (Fed. Cir. 2008)) indicate that a statutory “process” under 35 U.S.C. 101 must (1) be tied to “a particular apparatus”, or (2) transform underlying subject matter (such as an article or material) to a different state or thing. While the instant claims recite a series of steps or acts to be performed, the claims neither transform underlying subject matter nor positively tie to “a particular apparatus” that accomplishes the claimed method steps, and therefore do not qualify as a statutory process. The tied apparatus must perform the inventive steps, not the pre-solution activity or post-solution activity.

Regarding claim 1 as a representative claim recites “a MRI system” so it is tied to a machine. However, the tied-machine (MRI system) performs the pre-solution activity so claimed MRI system does not qualify as a "particular machine" as set forth in *Bilski* Court.

Furthermore, in claim 1, claimed “images” (line 3) does not represent any physical object, so claim 1 does not meet transformation test as set forth in *Bilski* Court.

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Likewise, claims 2-19 are also rejected for the same reasons as set forth in claim 1 above.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-4 and 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Muraki et al. (USPN 6,580,936, art of record IDS filed on 12/29/2005, referred as Muraki hereinafter).

Regarding claim 1, Muraki teaches a method for producing an image with a magnetic resonance imaging (MRI) system (see figures 1-9: note MRI device shown in figure 9 and MRI images shown in figures 1-4, 6 and 8), the steps comprising:

acquiring a plurality of images from a subject using the MRI system, each image being acquired with a different pulse sequence prescription that weights the acquired image data differently (see figures 1-9: note MRI device shown in figure 9 and MRI images shown in figures 1-4, 6 and 8; also refer to weighted images shown in figure 10 in together with col. 1 lines 14-49);

mapping each acquired image to a different color (see figures 3 and 6); and

combining each mapped color image to form a single composite color image (see figures 3 and 6: note “pseudo color image” shown in figure 3 and “color MRI” shown in figure 6).

Muraki further teaches: displaying the composite color image (see col. 1 lines 45-59, 55-60, and “pseudo color image” shown in figure 3 and “color MRI” shown in figure 6) as required by **claim 2**; analyzing the composite color image to identify a plurality of different tissue types

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therein (see col. 1 lines 45-60 and figure 2, and the use of color method for processing MRI images mentioned in col. 2 line 34 to col. 3 line 31) as required by **claim 3**; the analysis is a cluster analysis (decomposing) of pixels in the composite color image based on the color of the pixels (see figures 4-5 and col. 4 lines 17-29) as required by **claim 4**; the different pulse sequence prescriptions include a T₁ weighted prescription, a T₂ weighted prescription and a proton density weighted prescription (see weighted images shown in figure 10 in together with col. 1 lines 14-49) as required by **claim 6**; and the composite color image is analyzed based on the color of pixels in the composite color image to identify a plurality of different tissue types therein (see col. 1 lines 45-60 and figure 2, and the use of color method for processing MRI images mentioned in col. 2 line 34 to col. 3 line 31) as required by **claim 7**.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 5 and 8-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muraki as applied to claims 1-4 and 6-7, and in view of Merickel et al. (USPN 4,945,478, art of record IDS filed on 12/29/2005, referred as Merickel hereinafter).

The advanced statements with regard to Muraki in the preceding paragraph are incorporated hereinafter.

Regarding claim 5, while Muraki does not expressly teach that subject is an artery and the tissue types are found in atherosclerotic plaque, Muraki does teach diagnosis of MRI images of

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living body and living tissue to determine the form of the subject and state of the living tissue (see col. 1 lines 15-55).

However, Merickel, in the same field of endeavor that of medical image diagnosis, teaches using MRI to image artery (see figure 2 and column 23-24 and col. 3 lines 4-9) and diagnose such image to detect/find atherosclerotic plaque (see col. 1 lines 7-9, col. 3 line 67).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate such features as taught by Merickel in combination with Muraki in order to cure arteriosclerotic disease more effectively.

Merickel further teaches normalizing acquired images (see 54 and 55 of figure 10) as required by claim 8; registering the mapped color images before they are combined (see 52 of figure 10) as required by claim 12; performing a cluster analysis of pixels in the composite color image based on the color of the pixels (see Merickel: segmentation technique and clustering technique described in col. 6-7; and Muraki: figures 4-5 and col. 4 lines 17-29) as required by claim 13; performing an active contour analysis of the colors in said composite color image (see col. 8 line 30 and 67 of figure 12) as required by claim 14; and identifying the lumen of the blood vessel (see col. 6 lines 13-38) and identifying different tissue type surrounding lumen (see col. 7 lines 40-41) as required by claim 15.

Regarding claim 9, this claim is also rejected for the same reasons as applied to claim 5 above.

Regarding claim 10, both Muraki and Merickel teach the different pulse sequence prescriptions include a T_1 weighted prescription, a T_2 weighted prescription and a proton density weighted prescription (see Muraki: weighted images shown in figure 10 in together with col. 1

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lines 14-49; and Merickel: col. 3 lines 4-9 (note that different pulse sequence is applied in order different weighted image can be obtained).

Regarding claim 11, Merickel further teaches calculating a magnitude image for each acquired image (see Fourier Transform used in figure 13. This interpretation is consistent with applicant's disclosed specification, page 6 paragraph [0027]) and normalizing each magnitude image to equally weight the magnitudes (see col. 14 lines 3-20: note lowest frequency and grey level).

7. Claim 16 would be allowable if rewritten into independent form and to overcome the rejection under 35 USC 101 above.

8. Claims 17-19 would be allowable if rewritten to overcome the rejection under 35 USC 101 above.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Duy M. Dang whose telephone number is 571-272-7389. The examiner can normally be reached on Monday to Friday from 6:00AM to 2:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Matthew C. Bella can be reached on 571-272-7778. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dmd
9/2009

/Duy M Dang/
Primary Examiner, Art Unit 2624